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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,075	12/09/2005	Gang Zheng	1694.0580004/JMC/CMB	9659

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STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER

BLAND, LAYLA D

ART UNIT	PAPER NUMBER
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1623

MAIL DATE	DELIVERY MODE
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02/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,075	Applicant(s) ZHENG ET AL.	
	Examiner LAYLA BLAND	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,7,8 and 10-36 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,7,8,11-24 and 26-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,10 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/7/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is a response to Applicant's amendment dated December 28, 2007, wherein claims 5, 6, and 9 are cancelled and claim 1 is amended. Claims 1, 2, 10, and 25 are examined on the merits herein.

In view of the cancellation of claims 5, 6, and 9, all rejections made with respect to those claims in the previous office action are withdrawn.

In view of Applicant's amendment dated December 28, 2007, which requires that D is selected from the group consisting of BChIPP, BChIE6, and NIR664, the rejections of claims 1, 2, and 25 under 35 1012(e) as being anticipated by Tidmarsh; of claims 1 and 2 under 35 USC 102(e) as being anticipated by Dufes; of claims 1 and 2 under 35 USC 102(3) as being anticipated by Daishu; and of claim 25 under 35 USC 103(a) as being unpatentable over Dufes and Daishu are withdrawn.

After further review of the prior art, the rejection of claims 1, 2, 10 and 25 under 35 USC 112, first paragraph, for lacking full written description, is withdrawn. Glucose conjugates containing linker groups other than –NH– are taught in the prior art. Thus, it is assumed that the skilled artisan could, in fact, predict the operability of such species.

The following new rejection was necessitated by Applicant's amendment submitted December 28, 2007:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the recitation of claim 5. Claim 10 depends from claim 5, which has been cancelled. Claim 10 will be treated as though it depends from claim 1 for the purposes of examination.

The following rejection of record is modified for relevancy to the claims as presently amended and is maintained:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

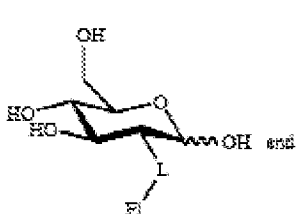
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 10, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tidmarsh et al. (US 6,989,140 B2, January 24, 2006) in view of Kozyrev et al. (Tetrahedron Letters 1996 Vol. 37, No. 36, pp. 6431-6434).

Tidmarsh et al. teach methods for cancer and pre-cancer detection by increased uptake of deoxyglucose conjugates in cancerous and pre-cancerous cells [see abstract]. Cancerous and pre-cancerous cells exhibit an enhanced rate of uptake of

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glucose fluorophore conjugates [column 4, lines 38-41]. The conjugates can be derived by chemically modifying 2-deoxyglucose, which is taken into and accumulated in cancerous cells and pre-cancerous cells compared to normal cells [column 4, lines 42-49]. After allowing the fluorophore glucose conjugate to accumulate in the cancerous cells, an examination can be made with a camera or other device to view or capture the fluorescence [column 4, lines 49-54]. Preferably, the fluorophore fluoresces upon excitation of light in the range of about 500 nm to 900 nm [column 6, lines 24-31]. The fluorophores can be attached to the deoxyglucose using a bifunctional linker group derived from functional groups such as $-NH_2$, $-NHNH_2$, $-ONH_2$, $-NHC(=O)NHNH_2$, $-OH$, $-CO_2H$, or $-SH$ [column 10, lines 26-45]. The fluorophore deoxyglucose conjugate can have the formula shown below, where L is a linker group and FI is a fluorophore [column 15, la]:



The conjugates can be administered in forms suitable for oral administration or parenteral administration and can include pharmaceutical carriers [column 17, lines 13-49].

Tidmarsh et al. do not teach a glucose conjugate with BChIPP.

Kozyrev et al. teach the conversion of unstable bacteriochlorophyll-a into stable bacteriochlorins [see abstract]. Photosensitizers with absorption near 800 nm are

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desired [page 6431, first paragraph]. Bacteriopurpurins 2 and 3 [page 6431, figure] were found to be very stable at room temperature with strong wavelength absorption at 813 nm and had “ideal” photochemical properties required for an effective photodynamic therapy agent [page 6431, last two lines and page 6432, first two lines].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare glucose conjugates with bacteriopurpurins, including those represented by 2 and 3 in the Kozyrev reference. Tidmarsh et al. teach that glucose conjugates with fluorophores are useful for cancer detection and Kozyrev et al. teach that bacteriopurpurins 2 and 3 have ideal properties for photodynamic therapy, including fluorescence within the desired wavelength range taught by Tidmarsh et al. Thus the skilled artisan could easily conceive of preparing a glucose conjugate of bacteriopurpurins taught by Kozyrev et al. and could predict that the resulting conjugate would be effective for cancer detection and photodynamic therapy.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one

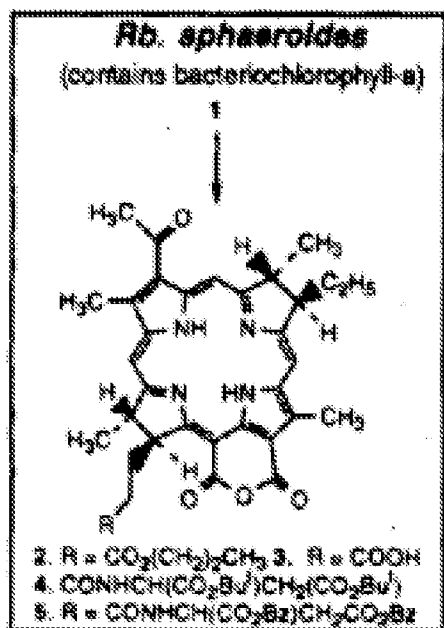
of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments filed December 28, 2007 have been fully considered but they are not persuasive.

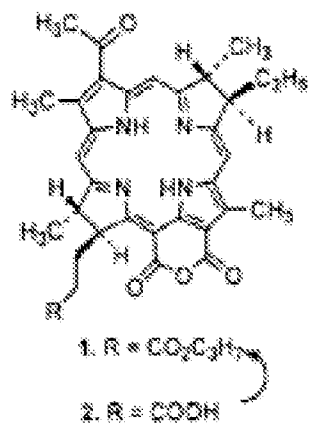
Applicant asserts that neither Tidmarsh nor Kozyrez teach or suggest the claimed D groups.

Claim 1 is drawn to a conjugate wherein D can be BChlPP (bacteriopurpurin-18). Kozyrez et al. teach the following compounds:



Kozyrez et al. do not refer to compound 2 as bacteriopurpurin-18. However, the same compound is called bacteriopurpurin-18 in the art. Chen et al. (J. Med. Chem. 2002, 45, 255-258, PTO-1449 submitted November 7, 2007) teach the following

compound and refer to it as bacteriopurpurin-18 **1** [page 256, Scheme 1 and first paragraph]:



Compound 2 of Kozyrez et al. appears to be the same as compound 1 of Chen et al., which is called bacteriopurpurin-18. Thus, Kozyrez et al. do teach one of the claimed D groups.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

This application contains claims 3, 4, 7, 8, 11-24, and 26-36 drawn to an invention nonelected with traverse in the reply filed on Jun 13, 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Layla Bland/

Examiner, Art Unit 1623

/Shaojia Anna Jiang/

Supervisory Patent Examiner, Art Unit 1623